

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: '318 PATENT INFRINGEMENT
LITIGATION

)
) Civil Action No. 05-356-KAJ
) (consolidated)

JOINT CLAIM CONSTRUCTION CHART

ATTORNEYS FOR PLAINTIFFS

Of Counsel:

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Kurt G. Calia
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Tel: 202-662-6000

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805

ASHBY & GEDDES
Steven J. Balick (I.D. # 2114)
John G. Day (I.D. # 2403)
Lauren E. Maguire (I.D. #4261)
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
Tel: 302-654-1888
Fax: 302-654-2067
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

ATTORNEYS FOR DEFENDANTS

Of Counsel:

George C. Lombardi
Taras A. Gracey
Lynn M. Ulrich
Mustafa A. Hersi
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Tele: (312) 558-5600
Fax: (312) 558-5700
lulrich@winston.com

PHILLIPS, GOLDMAN & SPENCE, P.A.
John C. Phillips, Jr. (I.D. #110)
Brian E. Farnan (I.D. #4089)
1200 North Broom Street
Wilmington, DE 19806
Tele: (302) 655-4200
Fax: (302) 655-4210
JCP@pgslaw.com

*Attorneys for Defendants
Barr Laboratories, Inc. and
Barr Pharmaceuticals Inc.*

Of Counsel:

Alan H. Bernstein
Robert S. Silver
Mona Gupta
William J. Castillo
Caeser, Rivise, Bernstein, Cohen &
Pokotilow, Ltd.
1635 Market St., 12th Floor
Philadelphia, PA 19103
Tele: (215) 567-2010

RICHARDS LAYTON & FINGER, P.A.
Frederick L. Cottrell, III (I.D. #2555)
Anne Shea Gaza (I.D. #4093)
One Rodney Square
920 N. King Street
Wilmington, DE 19801
Tele: (302) 651-7700
Fax: (302) 651-7701

*Attorneys for Defendant
Alphapharm Pty Ltd.*

Dated: December 4, 2006

Pursuant to the Court's January 12, 2006 Revised Scheduling Order (as amended by the Court on October 31, 2006), Plaintiffs Janssen Pharmaceutica, N.V., Janssen, L.P., and Synaptech, Inc. (collectively, "Plaintiffs") and Defendants Barr Pharmaceuticals, Inc., Barr Laboratories, Inc., and Alphapharm, Pty. (collectively "Defendants") submit the following Joint Claim Construction Chart providing their proposed constructions of claim terms of U.S. Patent No. 4,663,318 (hereinafter, "the '318 Patent") (Ex. A).

The parties agree that the Court need only construe certain terms in Claim 1 of the '318 Patent. The only other asserted claim, Claim 4 states: "A method according to claim 1, where in said administration is oral and in the range 10-2000 mg per day." Because there are no disputed terms in Claim 4 of the '318 Patent (separate from those in Claim 1 from which Claim 4 depends), it need not be considered separately.

CLAIM 1: A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically acceptable acid addition salt thereof.	
PLAINTIFFS' PROPOSED CONSTRUCTION AND SUPPORT	DEFENDANTS' PROPOSED CONSTRUCTION AND SUPPORT
<p>"Alzheimer's disease and related dementias"</p> <p>PLAINTIFFS' PROPOSED CONSTRUCTION: "presenile dementia and senile dementia of the Alzheimer's type"</p> <p>INTRINSIC EVIDENCE IN SUPPORT:</p> <p style="text-align: center;"><u>SPECIFICATION</u></p> <ul style="list-style-type: none"> Abstract; 1:34-38; 1:41-42; 1:45-50. <p style="text-align: center;"><u>FILE HISTORY</u></p> <ul style="list-style-type: none"> September 9, 1986 Amendment Responsive to Office Action of April 10, 1986 at pp. 2-5, and 9 (Ex. B). Hershenson and Moos, "Drug Development for Senile Cognitive Decline," <u>Journal of Medicinal Chemistry</u>, 29(7):1125-1130 (1986) (Ex. C). 	<p>"Alzheimer's disease and related dementias"</p> <p>DEFENDANTS' PROPOSED CONSTRUCTION:</p> <p><u>"Alzheimer's disease"</u>: Presenile dementia of the Alzheimer's type.</p> <p><u>"related dementias"</u>: Dementias related to Alzheimer's disease.</p> <p>INTRINSIC EVIDENCE IN SUPPORT:</p> <p>'318 Patent, 1:34-36'; '318 patent, claim 1; '318 patent, 1:45-46;</p>

<p>“A method of treating [Alzheimer’s disease and related dementias, defined above]”</p> <p>PLAINTIFFS’ PROPOSED CONSTRUCTION: “a method of alleviating the symptoms or deferring the decline associated with Alzheimer’s disease, including the cognitive impairment that is the core symptom of the disease, in a manner beneficial to the patient – that is, in a manner that is safe, tolerable, and produces clinically meaningful results”</p> <p>INTRINSIC EVIDENCE IN SUPPORT:</p> <p style="text-align: center;"><u>SPECIFICATION</u></p> <ul style="list-style-type: none"> • Abstract; 1:13-21; 1:34-38; 1:41-42; 1:45-50; 1:60-66; 2:7-18; 2:31-34; 2:58-66; and 4:3-5. <p style="text-align: center;"><u>FILE HISTORY</u></p> <ul style="list-style-type: none"> • September 9, 1986 Amendment Responsive to Office Action of April 10, 1986 at pp. 2-5, and 9. • Hershenson and Moos, “Drug Development for Senile Cognitive Decline,” <u>Journal of Medicinal Chemistry</u>, 29(7):1125-1130 (1986). 	<p>“A method of treating [Alzheimer’s disease and related dementias, defined above]”</p> <p>DEFENDANTS’ PROPOSED CONSTRUCTION:</p> <p>Administration of a drug product (i.e., galantamine) to improve the cognitive function or functional status of a patient with Alzheimer’s disease or related dementias.</p> <p>INTRINSIC EVIDENCE IN SUPPORT:</p> <p>‘318 Patent, 1:38-50, Dependent Claims 4 and 5.</p> <p>‘318 Patent File History, April 10, 1986, Examiner’s Rejection under 35 U.S.C. 112 at 3 (JAN RAZ-0000026) (Ex. D).</p> <p>‘318 Patent File History, Sept. 9, 1986, Amendment Responsive to Office Action at 2, 3, 6, and 9 (JAN RAZ-0000032, 0000033, 0000036, 0000039) (Exs. E, F, G, and H).</p>
<p>“a patient suffering from such a disease”</p> <p>PLAINTIFFS’ PROPOSED CONSTRUCTION: As explained in Plaintiffs’ Opening Brief on Claim Construction, Plaintiffs do not believe that Defendants have placed this claim term at issue. In the context of this claim, “a patient suffering from such a disease” means “a human suffering from Alzheimer’s disease and related dementias.”</p> <p>INTRINSIC EVIDENCE IN SUPPORT:</p> <p style="text-align: center;"><u>SPECIFICATION</u></p> <ul style="list-style-type: none"> • 1:34-38; 2:7-18; 3:6-8. <p style="text-align: center;"><u>FILE HISTORY</u></p> <ul style="list-style-type: none"> • September 9, 1986 Amendment Responsive to Office Action of April 10, 1986 at pp. 2-5. • Hershenson and Moos, “Drug Development for Senile Cognitive Decline,” <u>Journal of Medicinal Chemistry</u>, 29(7):1125-1130 (1986). 	<p>“a patient”</p> <p>DEFENDANTS’ PROPOSED CONSTRUCTION:</p> <p>A mammal, including a human.</p> <p>INTRINSIC EVIDENCE IN SUPPORT:</p> <p>‘318 Patent, 1:38-50; ‘318 patent, 2:45-57</p> <p>‘318 Patent File History, Sept. 9, 1986, Amendment Responsive to Office Action at 2 (JAN RAZ-0000032, 33) (Exs. E, F).</p>
<p>“a therapeutically effective amount”</p> <p>PLAINTIFFS’ PROPOSED CONSTRUCTION: “an amount sufficient to cause a therapeutically beneficial effect on symptoms of Alzheimer’s disease and related dementias”</p>	<p>“a therapeutically effective amount”</p> <p>DEFENDANTS’ PROPOSED CONSTRUCTION:</p> <p>An amount sufficient to produce the desired therapeutic change or effect in a patient.</p>

<p>INTRINSIC EVIDENCE IN SUPPORT:</p> <p style="text-align: center;"><u>SPECIFICATION</u></p> <ul style="list-style-type: none"> Abstract; 1:34-38; 1:41-42; 1:45-50; 1:60-66; 2:7-18; 2:31-34; 2:58-66; 4:3-5. <p style="text-align: center;"><u>FILE HISTORY</u></p> <ul style="list-style-type: none"> September 9, 1986 Amendment Responsive to Office Action of April 10, 1986 at pp. 2-5, and 9. 	<p>INTRINSIC EVIDENCE IN SUPPORT:</p> <p>'318 Patent, 1:38-50, Dependent Claims 4 and 5.</p> <p>'318 Patent File History, April 10, 1986, Examiner's Rejection under 35 U.S.C. 112 at 3 (JAN RAZ-0000026) (Ex. D).</p> <p>'318 Patent File History, Sept. 9, 1986, Amendment Responsive to Office Action at 2, 3, 6, and 9 (JAN RAZ-0000032, 0000033, 0000036, 0000039) (Exs. E-H).</p>
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ASHBY & GEDDES

/s/ Lauren E. Maguire

Steven J. Balick (I.D. #2114)
 John G. Day (I.D. #2403)
 Lauren E. Maguire (I.D. #4261)
 222 Delaware Avenue, 17th Floor
 P.O. Box 1150
 Wilmington, Delaware 19899-1150
 (302) 654-1888

On Behalf of All Parties

Of Counsel:

George F. Pappas
 Roderick R. McKelvie
 Christopher N. Sipes
 Kurt G. Calia
 COVINGTON & BURLING LLP
 1201 Pennsylvania Avenue, N.W.
 Washington, DC 20004
 Tel: 202-662-6000

Steven P. Berman
 Office of General Counsel
 Johnson & Johnson
 One Johnson & Johnson Plaza
 New Brunswick, NJ 08933
 Tel: 732-524-2805

ASHBY & GEDDES
 Steven J. Balick (I.D. # 2114)
 John G. Day (I.D. # 2403)
 Lauren E. Maguire (I.D. #4261)
 222 Delaware Avenue, 17th Floor
 P.O. Box 1150
 Wilmington, DE 19899
 Tel: 302-654-1888
 Fax: 302-654-2067
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

Attorneys for Plaintiffs

Of Counsel:

George C. Lombardi
Taras A. Gracey
Lynn M. Ulrich
Mustafa A. Hersi
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Tele: (312) 558-5600
Fax: (312) 558-5700
lulrich@winston.com

PHILLIPS, GOLDMAN & SPENCE, P.A.
John C. Phillips, Jr. (I.D. #110)
Brian E. Farnan (I.D. #4089)
1200 North Broom Street
Wilmington, DE 19806
Tele: (302) 655-4200
Fax: (302) 655-4210
JCP@pgslaw.com

*Attorneys for Defendants
Barr Laboratories, Inc. and
Barr Pharmaceuticals Inc.*

Of Counsel:

Alan H. Bernstein
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Caeser, Rivise, Bernstein, Cohen &
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Anne Shea Gaza (I.D. #4093)
One Rodney Square
920 N. King Street
Wilmington, DE 19801
Tele: (302) 651-7700
Fax: (302) 651-7701

*Attorneys for Defendant
Alphapharm Pty Ltd.*

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